

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
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World Health  
Organization

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Agenda Item 9

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON CONTAMINANTS IN FOODS

15<sup>th</sup> Session

Virtual

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### MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN AND ASSOCIATED SAMPLING PLANS (At Step 4)

(Prepared by the Electronic Working Group chaired by Brazil and co-chaired by India)

Codex members and observers wishing to submit comments at Step 3 on the MLs and sampling plans should do so as instructed in CL 2022/18-CF available on the Codex webpage<sup>1</sup>

#### BACKGROUND

1. The Codex Committee on Contaminants in Foods (CCCF) has been discussing the establishment of maximum levels (MLs) for total aflatoxins (AFs, namely the sum of aflatoxins B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub>) in cereals and cereal-based foods since 2013. At the 13<sup>th</sup> Session of CCCF (CCCF13, 2019) a discussion paper was presented to the Committee with data available in the GEMS/Food Database on the occurrence of AFs in cereal and cereal-based products, including cereal-based food for infants and young children, and focusing on maize, rice, sorghum, wheat and flours of these cereals.
2. The discussion paper showed<sup>2</sup> that there was a large dataset available on the occurrence of AFs in cereals and cereal-based products in the GEMS/Food Database (more than 17 000 samples), submitted mainly by the European Union (EU), Singapore and Canada. The discussion paper also demonstrated that the establishment of any MLs for AFs in maize grain, flour, meal, semolina and flakes derived from maize, husked and polished rice, wheat grain, flour, meal, semolina and flakes derived from wheat could greatly reduce total AFs exposure worldwide, as already stated by the Joint FAO/WHO Committee on Food Additives (JECFA) (TRS 1002-JECFA 83/11).
3. While there was general support for the establishment of maximum levels (MLs), observations were made that the work should be based on more geographically representative data. It was noted that occurrence data in cereals used for the analysis and the subsequent proposal for new work, relied heavily on data from only a few countries and regions. Although calls for data on the occurrence of AFs in cereals and cereal-based products have been made since 2014, the Committee pointed out that the available data were not sufficiently representative of cereal-based foods from all GEMS/Food cluster diets.

<sup>1</sup> Codex webpage/Circular Letters:  
<http://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/>.

Codex webpage/CCCF/Circular Letters:

<http://www.fao.org/fao-who-codexalimentarius/committees/committee/related-circular-letters/en/?committee=CCCF>

<sup>2</sup> Working documents considered by CCCF13 (2019), including CX/CF 19/13/15, are available from the CCCF13 website at:  
<https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCCF&session=13>

4. CCCF13 therefore agreed to establish an Electronic Working Group (EWG) chaired by Brazil and co-chaired by India to present at its next session proposals for MLs for total AFs in maize grain destined for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice (excluding parboiled rice), cereal-based food for infants and young children and sorghum. The Committee further agreed to include sorghum in the list noting that it was a staple food in many parts of the world and that once the work on the MLs for the food categories mentioned above were completed, the proposal of MLs for other cereals and cereal-based products should be considered. There was also agreement that a call for data should be issued on whole wheat flour and parboiled rice to better assess whether these food categories should be added later.<sup>3</sup>
5. The 42<sup>nd</sup> Session of the Codex Alimentarius Commission (CAC42, 2019) approved the new work as proposed by CCCF13.<sup>4</sup>
6. CCCF14 was postponed from May 2020 to May 2021 due to the COVID-19 pandemic and in view of the additional time at the disposal of the Committee, an interim report of the EWG was published as CX/CF 20/14/10-Part I.
7. After the discussion of the document in CCCF14, the Committee pointed out that, even though a lot of data calls have been made, most data still came from a few countries. Therefore, it was agreed to issue another call for data on all the food categories under discussion with a view to obtaining more geographically representative data and to include a request for country of origin and if possible to differentiate between maize for food or feed with the aim to finalize the MLs next year (CCCF15, 2022) and if no new data were received, the current dataset would be used as the basis for the establishment of the MLs.
8. The Committee also requested to the EWG to: 1) verify the presence of outliers and decide whether they should be excluded or not from the dataset; 2) evaluate year to year and regional variations of data submitted; 3) To work in close collaboration with the EWG on data management and 4) To consider whether the ML would be set for maize for further processing or maize for direct human consumption. Another point raised in the discussion was the ability of food aid programs to purchase and provide food to vulnerable populations considering the ML proposed in the document. It was recommended to consider the food security when evaluating lower MLs for staple food such as cereals and cereal-based products.
9. CCCF14 agreed that the EWG should keep working on these categories, with the aim to finalize the MLs at CCCF15.<sup>5</sup>

#### **KEY POINTS RAISED IN THE ELETRONIC WORKING GROUP**

10. In developing this draft, the following points were raised by the EWG:
11. Some countries questioned about the geographic representation of the samples

*Although calls for data on the occurrence of AFs in cereals and cereal-based products have been made since 2014, data available at the GEMS/Food Database does not represent all Cluster Diets. This difficulty has been pointed out since the first discussion paper on the occurrence of Aflatoxins in cereals and its products was presented and, to address this issue, several calls for data have been made in the past eight years. Even though a lot of effort have been made to propose limits using a representative dataset, this information did not become available for all products considered in this document.*

*Notwithstanding, considering the toxicological relevance of AFs and how the establishment of MLs for these food categories could greatly reduce human exposure to these mycotoxins, CCCF agreed to start a new work on the establishment of MLs for maize grain destined for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice (excluding parboiled rice), cereal-based food for infants and young children and sorghum, using data available at GEMS/Food. CAC42 approved<sup>3,4</sup> this work and established a deadline for CCCF for the completion of this task.*

*It's also important to remember that in the last CCCF meeting it was agreed to request another call for data on all categories under discussion in this document and, if no data was submitted, the MLs would be finalized on the existing data set.*

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<sup>3</sup> REP19/CF13, paras. 146-155, Appendix IX

<sup>4</sup> REP19/CAC42, Appendix V

<sup>5</sup> REP21/CF14, paras. 107-138

12. Some countries and observers pointed out that MLs proposed may constrain the capacity of humanitarian agencies of purchasing and delivering foods all over the world.

*The last CCCF meeting recommended that the EWG should assess the impact of lower MLs on food aid/food security, particularly cereal products for infants and young children. In a meeting held between representatives of the EWG and the World Food Program (WFP), shortly after CCCF meeting, the organization of the document was clarified, and it was suggested that Food Aid agencies should submit their quality control data to GEMS/Food Database through countries where they buy products to the humanitarian programmes. After the first draft of this document was circulated, WFP added some information in its comments that were considered for the proposal of ML for cereal-based foods for infants and young children.*
13. One country raised concerns about the availability of collaboratively validated aflatoxin methods that are suitable for analysis within the MLs proposed in this document, mainly for the proposal of 2 µg/kg for cereal-based foods for infants and young children.

*Considering the comments received through the EWG, the ML of 2 µg/kg for cereal-based foods for infants and young children was not considered viable, mainly because the constraints faced by Food Aid Agencies to purchase products within this limit. Therefore, higher limits are being suggested for cereal-based foods for infants and young children, eliminating such methodological problems. Nevertheless, some countries reported that lower MLs are in force, so it is possible that the results of collaborative assays for the methods used are available. If the Committee agrees in adopting lower limits, such as 2 µg/kg, it is suggested that the Codex Committee on Methods of Analysis and Sampling (CCMAS) should be questioned about the availability of such validated methods.*
14. One country requested that its rice data mapped as GC 0649 in the *Classification of Food and Feed (CXA 4-1989)* should be included in the rice polished category.

*In this document, following orientations of CL 2021/78-CF<sup>1</sup>, data that were not possible to define in which category it belonged – for example, rice samples classified with the food code GC 0649, but with no further information that could clarify if it was husked, polished or other type of rice - were removed from the dataset. In this case, as the country clarified that unspecified samples would fall under the polished rice category, data previously excluded were re-entered into the database used in the preparation of this document. This change was only made for the country that requested the modification, since it was not possible to ensure that the same thing happened to other countries.*
15. One country pointed out that several reported means of lower bound in occurrence tables were greater than the 95th percentile of the lower bound.

*The values were double checked and were corrected. This difference between means and 95th percentiles happened in a dataset when only a few samples had higher concentration values. For example, when the husked rice data submitted in 2014 was reviewed, it showed that 10 out of 81 samples were positive, the mean of the lower bound was 4.25 µg/kg, but the P95th was 2.83 µg/kg. The median of the lower bound of this dataset was 0.0 µg/kg, indicating that 50% of samples were below the limit of quantification (LOQ) of the methods used in the analysis. One sample was contaminated with 290 µg/kg, which highlights the difficulty of using the mean when working with skewed data. The use of median of the lower bound was discussed in previous documents of Aflatoxins occurrence and was discarded since most of medians estimated from the datasets available showed a value of 0 µg/kg.*
16. One country pointed out that the maximum concentration level of aflatoxins reported for its samples of flour, meal, semolina and flakes derived from maize seemed to be high considering their records.

*Data were reviewed and it was identified that formulas used to aggregate individual data (same serial number and different entries for each aflatoxin or sum of aflatoxins) were adding multiple times the results of some samples with more than one entry in the database. For example, when data was submitted for individual AFB1 and AFB2, as well as for the sum of AFB1 and AFB2 for the same sample, the formula used did not exclude one of them and ended up adding the values of the three entries. This error was corrected in the database used in this document and this is one of the reasons why concentration levels found in this document may be slightly different from the first draft circulated.*
17. One country questioned how samples for human consumption were distinguished from samples destined to animal feed.

*In the last meeting, it was agreed upon a new call for data on all categories under discussion in this document with the request of submission of any kind of information that could make possible to differentiate maize for food or feed.*

*Data used in this document were re-extracted from the GEMS/Food Database, to allow the incorporation of new information (new submissions, different exclusion criteria, removal of samples that were not for human consumption or complementation of information from samples already submitted). Even with this new extraction, there was no information that could ensure that samples analysed were for human consumption and not for animal feed.*

*Considering previous discussions that countries have already pointed out that it would not be possible to distinguish, in international trade, samples intended for human consumption from samples destined for animal feed, in this document, only samples that expressed that they were intended for animal consumption were removed. The remaining samples were considered as intended for human consumption.*

18. Some countries questioned whether the ML proposed for maize would be set for maize for further processing or maize for direct human consumption.

*Dataset extracted from the GEMS/Food Database was analysed and it was noticed that, unlike rice that had different classification for its types (GC 0649 – Rice; CM 0649 - Rice, husked; CM 1205- Rice, polished), for maize, all samples were mapped to the GC 0645 category (Maize – several cultivars, not including popcorn and sweetcorn).*

*Looking into the local food name column, it was not possible to differentiate maize that will be destined for further processing from maize for direct human consumption, as the most frequent descriptions were maize, corn, corn grain, maize grain, and raw corn.*

*Considering that it was not possible to establish a solid criterion to distinguish maize for further processing from maize that are ready-to-eat, it was decided to consider all samples submitted as products destined for further processing. This decision was taken to maintain consistency with already established limits, such as Deoxynivalenol (DON) in cereals grains, and also considering usual habits of consumption of maize that normally requires a kind of processing before consumption.*

19. One country asked for clarification as to whether the limits would be established in which results basis.

*Dataset available only support the establishment of limits for “as is” basis.*

20. One country requested clarification why negative samples (<LOQ) analysed with methods that reported LOQs higher than the first ML tested were removed from the assessment.

*Whereas the available dataset consisted mainly of low percentage of positive samples (most food category had incidence levels around 10%), if negative samples analysed with methods that reported high LOQs were maintained in the dataset they would lead to an even lower incidence mean levels, which could mislead the analysis, as the committee would be under the impression that the contamination levels were too low, when, actually, the methods used were not capable to detect samples contaminated with lower levels of AFs.*

*Therefore, to establish a cut off, the value of the first ML tested (i.e. the highest one) for each food category was selected.*

21. One country requested clarification on the detailing of the infant food category.

*Although the cereal-based food for infants and young children standard is divided into different categories, data available at the GEMS/Food did not allow making this distinction. A few samples described the cereal used to prepare the cereal-based food (maize, rice, wheat), but since this was uncommon, it was not possible to divide this category according to the cereal used in the production. The dataset was composed mainly by powdered cereals, but also included samples of crackers and biscuits intended to infants and young children.*

22. One country suggested to include a footnote indicating that the proposed ML for maize grain, destined for further processing does not apply to corn for wet milling.

*Considering that the following footnote was included “ ‘Destined for further processing’ means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption.*

*Codex members may define the processes that have been shown to reduce levels”, the Committee should decide if it is still important to include a footnote regarding the wet milling process.*

## CONCLUSIONS

### Maximum levels

23. The present document was prepared considering data submitted to GEMS/Food, collected between 2011 and 2021. The proposed MLs were defined considering the following: 1) Hypothetical MLs were chosen following a geometric progression (the CL 2021/78-CF) and subsequent suggestions from the EWG; 2) The proposed MLs were selected considering both AFs intake reduction and samples rejection; 3) Year to year, and geographic variation and Food Aid data were considered when proposing MLs to ensure food security (MLs that did not reject more than 5% of samples in most groups); 4) Outliers were not removed since CCCF has not yet agreed upon a procedure to deal with outliers in datasets of heterogeneous distributed contaminants and considering the possibility of samples being really contaminated with high levels of AFs.
24. Data used in this document differs from the paper presented in last meeting because, for example the period selected was not the same, there was new data submission and the exclusion criteria were more rigorous, according to the CL 2021/78-CF (More details in Appendix II, paragraphs 3 and 4). Different MLs were proposed considering the profile of contamination of the food category and based on a geometric progression (CL 2021/78-CF). After the first draft was circulated, a few countries suggested testing different limits other than the geometric progression tested and all of them were incorporated into the final version of the paper.

### Sampling plans

25. CCCF14 decided to develop sampling plans associated with the MLs. Nevertheless, it is recommended to set MLs before moving forward with the sampling plans and the methods of analysis, because they depend on the MLs. Additionally, it is advisable to decide the following issues:
  - i. If the sampling plan and the decision rule should be aligned with the sampling plans for mycotoxins already mentioned in *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995) or with the *General Guidelines on Sampling* (CXG 50-2004) once they are finalized by the Codex Committee on Methods of Analysis and Sampling (CCMAS).
  - ii. If CCMAS should be consulted regarding how to establish performance criteria for a sum of components (AFB1, AFB2, AFG1 and AFG2) in the different matrices considering that AFB1, AFB2, AFG1 and AFG2 are not distributed equally and presents different profile in the various cereal grains.

## RECOMMENDATIONS

26. CCCF is invited to:
  - a. consider the proposed MLs for the selected food categories as shown in Appendix I based on the conclusions provided in paragraphs 22 and 23 and the data/information provided in Appendix II and their readiness for final adoption by CAC45 (2022); and
  - b. suspend the development of sampling plans until finalization of the MLs and in addition, provide advice on the points raised in paragraph 25(i-ii).

**APPENDIX I**  
**(For comments)**

**PROPOSED MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN  
CERTAIN CEREALS AND CEREAL-BASED PRODUCTS  
INCLUDING FOODS FOR INFANTS AND YOUNG CHILDREN**

<b>Food category</b>	<b>ML<sup>a</sup></b>	<b>Sample rejection (%)</b>
Maize grain, destined for further processing <sup>b,c</sup>	30 µg/kg	3.7
Flour, meal, semolina and flakes derived from maize	20 µg/kg	1.0
Husked rice	25 µg/kg	1.9
Polished rice	5 µg/kg	0.8
Sorghum grain, destined for further processing <sup>a</sup>	15 µg/kg	0.9
Cereal-based Food for infants and young children <sup>d</sup>	10 µg/kg	0.14

<sup>a</sup>Limits proposed on an “as is” basis; <sup>b</sup>“Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels; <sup>c</sup>Does not apply to maize destined for animal feed; <sup>d</sup>All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

**APPENDIX II**  
**(For information)**

**INTRODUCTION**

1. Aflatoxins (AFs) are considered the most important naturally occurring group of mycotoxins in the world's food supply. AFs (B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub>) were classified as human liver carcinogens by an evaluation conducted by JECFA, with AFB<sub>1</sub> being considered the most potent one (FAO/WHO, 1998; FAO/WHO, 2017). No tolerable daily intake was proposed since they are genotoxic carcinogens. JECFA noted, at its last toxicological evaluation on aflatoxins (FAO/WHO, 2017), that rice, wheat, and sorghum needed to be addressed in future risk management activities for aflatoxins, considering their contribution to aflatoxin exposure in some parts of the world where these cereals are consumed as staple foods in the diet.
2. Since the complete elimination of aflatoxins from the food supply is not feasible, measures should be taken to control and manage worldwide contamination. At CCCF13 (2019), it was noted that the Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals (CXC 55-2004) was adopted in 2003 and revised in 2017 and the logical next step for the CCCF was to establish MLs for aflatoxins in some cereal and cereal based products. Maximum Levels (MLs) for total aflatoxins have been established by the Codex Alimentarius Commission for almonds, Brazil nuts, hazelnuts, peanuts intended for further processing, pistachios, and dried figs (CXS 193-1995). The focus of this document is to review occurrence data submitted to the GEMS/Food Database and to propose additional MLs for total aflatoxins in cereals and cereal-based products, including food for infants and young children.

**DATA ANALYSIS**

3. Data on aflatoxins levels in maize grain for further processing, flour, meal, semolina, and flakes derived from maize, husked and polished rice, sorghum grain and cereal-based food for infants and young children were obtained from the GEMS/Food Database. After the last meeting, JECFA issued another call for data on all categories under discussion in this document. Considering that this call included a special request for the indication of country of origin and to provide any information that could allow the differentiation between maize for food or feed, the data was re-extracted from the GEMS/Food Database to allow the incorporation of the new information provided by country members in this document.
4. Unlike last year when data from 2007 to 2019 were included (CX/CF 21/14/10-Part I-App.II), this year data for samples analysed between 2011 and 2021 were extracted from the database for analysis. Worldwide occurrence of aflatoxins in cereals and products thereof was evaluated using data extracted from the GEMS/Food Database as of October 26<sup>th</sup>, 2021. Comparing with the data presented last meeting, the new extraction included samples from African Union (maize grain and sorghum), Montenegro (maize grain, flour, meal, semolina and flakes derived from maize and polished rice), Rwanda (maize grain and cereal-based food for infants and young children), North Macedonia (flour, meal, semolina and flakes derived from maize), Indonesia (husked and polished rice), Mali (husked rice), Canada (sorghum), European Union (sorghum), India (sorghum) and Thailand (cereal-based food for infants and young children). Differences found between data presented in this document and data discussed last year are due mainly to new submissions and different exclusion criteria adopted (time frame, composition of each category).
5. First, data were individually analysed and grouped into categories according to their listed "food name, food code and local food name". Final, food categories were created considering the data available in the GEMS/Food Database and the CCCF grouping recommendations. The following data were removed from the dataset:
  - a) Data that did not meet the basic criteria - for example, samples classified as maize grain but described in the local food name as canned maize (i.e., sweet corn consumed as a vegetable rather than as a cereal grain);
  - b) Data that was not possible to define in which category it belongs – for example, rice samples classified with the food code GC 0649, but with no further information that could clarify if it was husked, polished or other type of rice;
  - c) Aggregated samples (i.e., samples reported as summary statistics rather than individually);
  - d) Samples that did not report limit of quantification (LOQ) or limit of detection (LOD) values and that did not have quantifiable results;
  - e) Samples with LOQs higher than the highest hypothetical ML considered for each food category in this document;

- f) For aflatoxins, some samples included information on individual aflatoxin (AFB<sub>1</sub>, AFB<sub>2</sub>, AFG<sub>1</sub>, AFG<sub>2</sub>), the sum of AFB<sub>1</sub> plus AFB<sub>2</sub> and total aflatoxins, which generated up to 6 entries per sample. In such cases, data were gathered according to the “serial number” provided. Samples that reported results only for AFB<sub>2</sub>, AFG<sub>1</sub> or AFG<sub>2</sub> were excluded when it was not possible to sum individual content to yield a total aflatoxin content using the “serial number”. When only one entry was found for each serial number, such as reported values only for AFB<sub>1</sub> or only the sum of AFB<sub>1</sub> + AFB<sub>2</sub> were provided, the data was maintained in the dataset in its original form. Considering this information, it was not possible to keep a record of the samples excluded from the dataset, since just one sample could lead to the insertion of up to six lines in the dataset
6. Potential outliers were not removed since aflatoxins are not homogeneously distributed and therefore it is possible that samples with high AFs content could be found in the market. Besides that, the few extreme values maintained in the dataset did not impact the proposal of MLs since they did not impact significantly the 95 percentiles. The treatment of outliers in the data for mycotoxins should be further addressed in the ongoing discussion at the EWG on Data Management and Quality (CL 2021/78-CF), taking into account mycotoxins' heterogeneous distribution in food samples.
7. Only samples intended for human consumption were maintained in the dataset, i.e., animal feed samples were not included in the analysis. Lower bound AFs content were estimated considering samples below the reported LOQ as zero, since the positive detection rate for almost all food categories were less than 20%.

**PROPOSED MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CERTAIN CEREALS AND CEREAL-BASED PRODUCTS, INCLUDING FOOD FOR INFANTS AND YOUNG CHILDREN**

8. In order to propose ML for total aflatoxins, data for each food category were organized in three different tables, containing information on the worldwide AFs occurrence level, based on data submitted by member countries, the year-to-year variability during the period analysed and the effects of the implementation of different hypothetical MLs on AFs intake and sample rejection. Different MLs were proposed using a geometric progression and considering the profile of contamination of the food category. MLs suggested by the EWG were incorporated into the document.
9. Since the risk assessment for AFs was conducted by JECFA in 2017 (JECFA49), dietary exposure to aflatoxins was estimated in this document only to support the risk management decisions. Dietary exposure to aflatoxins through the consumption of maize grain for further processing, flour, meal, semolina and flakes derived from maize, husked and polished rice, and sorghum grain for further processing were estimated using the GEMS/Food occurrence data and mean consumption data obtained from the 17 GEMS/Food Cluster Diets. Consumption data were chosen to best represent the food categories evaluated. Annex I of Appendix I shows countries that belong to each GEMS/Food Cluster and consumption data for each cluster diets can be found in Annex II. Dietary exposure to AFs through the consumption of food for infants and young children was evaluated using Canadian Community Health Survey data since information for this category is not available in the GEMS/Food Cluster Diets.
10. Maize grain. Tables 1, 2 and 3 show data on the occurrence and content of AFs in maize grain destined for further processing. A total of 1,158,298 samples were analysed and 10.6% were positive for one or more AFs. The mean of positive samples was 58.6 µg/kg, mean and the 95<sup>th</sup> percentile (P95) of the lower bound were, respectively, 6.23 µg/kg and 19 µg/kg. Most samples analysed were submitted by the USA (99.11%). The highest lower-bound mean content was found in samples submitted by the Rwanda (20.43 µg/kg), African Union (11.96 µg/kg) and USA (6.16 µg/kg). In Table 2, a temporal analysis data from the last 10 years (2011 to 2021) is provided; data where the year of sampling was not specified was not included. Based on the combined, or worldwide datasets, 2021, 2020 and 2012 showed the highest incidence levels of AFs, with respectively, 99.1%, 89.5% and 27.5% of samples containing detectable content of one or more AFs. Table 3 shows that the mean of the lower bound ranged from 1.0 µg/kg in samples submitted by Asian countries to 20.1 µg/kg on samples from African countries.



**Table 1.** GEMS/Food data on the occurrence and content of AFs in maize grain destined for further processing.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>b</sup> (%)	Positive samples ( $\mu\text{g}/\text{kg}$ ) <sup>c</sup>		Lower bound <sup>d</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
African Union	10/16 (62.5)	19.14 (0.35-76.41)	5.12	11.96	64.0
Brazil	0/53 (0)	<LOQ	<LOQ	<LOQ	0.00
Canada	1/114 (0.88)	124	124	1.09	0.00
European Union	494/2950 (16.75)	7.42 (0.02-226)	1.92	1.24	3.00
Philippines	2/7 (28.57)	12.15 (9.47-14.83)	12.15	3.47	13.2
Montenegro	0/6	<LOQ	<LOQ	<LOQ	0.00
Rwanda	7077/7080 (99.96)	20.44 (2-207.7)	13.30	20.43	62.4
Saudi Arabia	2/37 (5.41)	7.51 (5.1-9.92)	7.61	0.41	1.8
Singapore	0/16 (0)	<LOQ	<LOQ	<LOQ	0.0
Thailand	0/16 (0)	<LOQ	<LOQ	<LOQ	0.0
USA	115,670/1,148,011 (10.1)	61.2 (0.02-9,928)	18.00	6.2	18.0
<b>Total</b>	<b>123,256/1,158,298 (10.6)</b>	<b>58.6 (0.02-9,928)</b>	<b>17.00</b>	<b>6.24</b>	<b>19.0</b>

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>Samples <LOQ analysed with methods with LOQ higher than 40  $\mu\text{g}/\text{kg}$  were removed; <sup>c</sup>LOQ of the methods ranging from 0.001 to 22.94  $\mu\text{g}/\text{kg}$ ; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 2.** GEMS/Food data on the occurrence and content of AFs in maize grain destined for further processing organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - $\mu\text{g}/\text{kg}$ <sup>b</sup>		Lower bound <sup>c</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
2011	21,424/160,563 (13.3)	78.3 (0.2-3,200)	37.00	10.5	62.0
2012	44,356/161,287 (27.5)	83.6 (0.1-6,117)	30.00	23	96.0
2013	21,859/150,557 (14.5)	38.4 (0.1-9,928)	15.00	5.6	20.0
2014	5,558/102,535 (5.4)	16.3 (0.2-2,400)	9.00	0.9	.0
2015	3,825/102,572 (3.7)	48 (0.3-5,341)	8.00	1.8	0.0
2016	4,658/120,353 (3.9)	38 (0.02-1,000)	9.00	1.5	0.0
2017	6,962/122,793 (5.7)	38.1 (0.1-8447)	12.00	2.2	6.0
2018	7,417/146,694 (5.1)	18.9 (0.02-919)	9.00	1.0	2.7
2019	4,624/88,189 (5.2)	18.5 (0.2-997)	10.00	1.0	5.0
2020	1473/1645 (89.5)	20.4 (0.3-207.7)	13.30	18.2	59.4
2021	1,100/1,110 (99.1)	21.1 (7.0-162.9)	13.70	20.9	62.1
<b>Total</b>	<b>123,256/1,158,298 (10.6)</b>	<b>58.6 (0.02-9,928)</b>	<b>17.00</b>	<b>6.24</b>	<b>19.0</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 40  $\mu\text{g}/\text{kg}$  were removed; <sup>b</sup>LOQ of the methods ranging from 0.001 to 22.94  $\mu\text{g}/\text{kg}$ ; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 3.** GEMS/Food data on the occurrence and content of AFs in maize grain destined for further processing organized by continent.

Continent	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - $\mu\text{g}/\text{kg}$ <sup>b</sup>		Lower bound <sup>c</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
Africa	7087/7096 (99.9)	20.4 (0.35-207.7)	13.30	20.41	62.4
Americas	115,587/1,148,012 (10.1)	61.1 (0.02-9928)	18.00	6.2	18.0
Asia	21/111 (18.9)	5.1 (0.05-16.2)	9.70	1.0	2.0
Europe	1,070/4,045 (26.5)	7.5 (0.02-226)	1.92	2.0	3.0
<b>Total</b>	<b>123,256/1,158,298 (10.6)</b>	<b>58.6 (0.02-9,928)</b>	<b>17.00</b>	<b>6.24</b>	<b>19.0</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 40  $\mu\text{g}/\text{kg}$  were removed; <sup>b</sup>LOQ of the methods ranging from 0.001 to 22.94  $\mu\text{g}/\text{kg}$ ; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

11. Table 4 shows the impact of the implementation of MLs on exposure and on rejection rates for AFs in maize grain destined for further processing. The intake reduction was estimated for the Cluster Diet with the highest consumption of the food category being examined (worst case scenario -G06) (see Annex I for details on this Cluster Diet), using mean lower bound concentration and the sample rejection rate and was calculated using all samples in the dataset. Six different hypothetical MLs were considered, based on the AFs contamination profile of maize grain data submitted to the GEMS/Food Database. Among the six values considered, 40  $\mu\text{g}/\text{kg}$ , 30  $\mu\text{g}/\text{kg}$  and 20  $\mu\text{g}/\text{kg}$  seem to be the more suitable values, since for those limits, the majority of countries and years would not reject more than 5% of the samples. For example, if a ML of 10  $\mu\text{g}/\text{kg}$  was considered, only 63% of the countries that submitted samples to GEMS/Food and 54% of the years analysed would be in accordance to this limit. Therefore, to assess which of the limits would be the most appropriate, the impact on rejection rates of countries/regions and years that presented a P95 higher than 20  $\mu\text{g}/\text{kg}$  were evaluated (Table 5).

**Table 4.** Effect of hypothetical MLs on aflatoxins intake through the consumption of maize grain for Cluster G06 (highest consumption pattern).

ML ( $\mu\text{g}/\text{kg}$ )	Mean lower bound AF ( $\mu\text{g}/\text{kg}$ )	Intake (ng/kg bw per day) <sup>a</sup>	Intake reduction (%)	Sample rejection (%) <sup>b</sup>
No limits	6.236	1.2815	-	-
40	1.030	0.2117	83.5	3.4
30	0.904	0.1859	85.5	3.7
20	0.643	0.1321	89.7	4.7
10	0.280	0.0576	95.5	7.1
5	0.058	0.0119	99.1	9.8
2.5	0.001	0.0001	100	10.6

<sup>a</sup>Consumption data used: maize, raw; G06=12.33 g/person (mean consumption) (see Annex II). <sup>b</sup>Percentage of samples above proposed MLs for AFs considering data submitted by all member countries for this food category.

**Table 5.** Rejection rates (%) estimated for MLs under consideration for aflatoxins in maize grain destined for further processing.

GEMS/Food data (Country/Region/year) <sup>a</sup>	ML ( $\mu\text{g}/\text{kg}$ ) <sup>b</sup>		
	40	30	20
African Union	12.5	12.5	18.8
Rwanda	10.2	13.5	20.5
2011	6.5	6.9	8.2
2012	12.5	13.6	17.4
2020	9.1	12.0	18.3
2021	10.6	13.8	20.7

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>The impact of MLs on samples rejection were evaluated for Country/Region that presented a P95>20 µg/kg).

12. Among the three MLs presented in Table 5, the establishment of an ML of 30 µg/kg seems to be the best option, considering a compromise between intake reduction (Table 4; 85.5%; G06) and rejection rates. A ML of 30 µg/kg would keep rejection rates under 15% for countries/regions/years evaluated in Table 5 (most critical for the establishment of this ML), while a ML of 20 µg/kg would give rejection rates higher than 15% for most data evaluated. Considering the adoption of a ML of 20 µg/kg for maize grain, the rejection rate would exceed 5% for samples submitted by African Union (18.8%) and Rwanda (20.5%) and for samples collected in 2011 (8.2%), 2012 (17.4%), 2020 (18.3%) and 2021 (20.7%). Even though the rejection rates are exceeding 5% for a few countries and years, the ML of 30 µg/kg seems suitable considering that the ML is being proposed for maize for further processing and AFs content could be greatly reduced during the dry milling process, as already discussed in CCF8.
13. Flour, meal, semolina and flakes derived from maize. Tables 6, 7 and 8 show data on the occurrence level of AFs in flour, meal, semolina and flakes derived from maize. A total of 5,175 samples were submitted to the GEMS/Food Database and 11.4% were positive for one or more AFs. Mean of positive samples was 16.06 µg/kg, mean and the P95 of the lower bound were respectively 1.84 µg/kg and 1.60 µg/kg. Most samples analysed came from the European Union (55.5%), Canada (19.3%) and the USA (18.7%). The highest mean level of the lower bound was found in samples submitted by Singapore (15.38 µg/kg) and the USA (3.64 µg/kg). The years of 2013, 2014 and 2021 showed the highest incidence levels of AFs, with, respectively, 29% and 16%, of samples being positive.

**Table 6.** GEMS/Food data on the occurrence and content of AFs in flour, meal, semolina and flakes derived from maize.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>b</sup> (%)	Positive samples - µg/kg <sup>c</sup>		Lower bound <sup>d</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
Argentina	1/1 (100)	0.13	0.13	0.13	0.13
Brazil	0/16 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Canada	77/997 (7.7)	12.90 (0.08-91.40)	2.90	1.00	1.52
European Union	223/2874 (7.8)	4.78 (0.01-790)	0.60	0.37	0.41
North Macedonia	0/49 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Philippines	1/3 (33.3)	6.68 (6.68-6.68)	6.68	2.23	6.01
Montenegro	0/13 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Singapore	108/255 (42.4)	36.32 (0.15-1281)	0.70	15.38	19.96
Thailand	0/1 (0.0)	<LOQ	<LOQ	<LOQ	0.0
USA	182/966 (18.8)	19.34 (0.24-371.80)	4.00	3.64	9.80
<b>Total</b>	<b>592/5175 (11.4)</b>	<b>16.06 (0.01-1281)</b>	<b>1.24</b>	<b>1.84</b>	<b>1.60</b>

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>Samples < LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>c</sup>LOQs of the methods ranging from 0.01 to 25 µg/kg; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 7.** GEMS/Food data on the occurrence and content of AFs in flour, meal, semolina and flakes derived from maize, organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - $\mu\text{g}/\text{kg}$ <sup>b</sup>		Lower bound <sup>c</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
2011	34/344 (9.9)	3.06 (0.10-26.80)	1.35	0.30	1.18
2012	93/632 (14.7)	5.90 (0.03-52.31)	3.09	0.87	5.00
2013	97/332 (29.2)	2.98 (0.17-17.40)	1.17	0.87	4.59
2014	62/383 (16.2)	33.10 (0.20-476)	1.17	5.36	2.16
2015	32/343 (9.3)	26.14 (0.02-348)	1.17	2.44	1.13
2016	69/615 (11.2)	31.24 (0.01-790)	0.97	3.50	1.14
2017	52/641 (8.1)	24.47 (0.06-394)	1.27	1.98	0.80
2018	71/856 (8.3)	4.68 (0.05-73.80)	0.64	0.39	0.50
2019	21/452 (4.6)	3.86 (0.13-26.30)	1.40	0.18	0.00
2020	47/490 (9.6)	36.17 (0.08-1281)	1.89	3.47	1.84
2021	14/87 (16.1)	9.81 (0.28-50.45)	3.64	1.58	10.13
<b>Total</b>	<b>592/5175 (11.4)</b>	<b>16.06 (0.01-1281)</b>	<b>1.24</b>	<b>1.84</b>	<b>1.60</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20  $\mu\text{g}/\text{kg}$  were removed; <sup>b</sup> LOQs of the methods ranging from 0.01 to 25  $\mu\text{g}/\text{kg}$ ; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 8.** GEMS/Food data on the occurrence and content of AFs in flour, meal, semolina and flakes derived from maize, organized by continent.

Continent	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - $\mu\text{g}/\text{kg}$ <sup>b</sup>		Lower bound <sup>c</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
America	260/1980 (13.09)	17.36 (0.08-372)	3.73	2.28	5.68
Asia	109/259 (42.08)	36.05 (0.15-1281)	0.73	15.17	18.40
Europe	223/2936 (7.60)	4.78 (0.01-790)	0.60	0.36	0.40
<b>Total</b>	<b>608/5304 (11.46)</b>	<b>16.06 (00.1-1281)</b>	<b>1.24</b>	<b>1.84</b>	<b>1.60</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20  $\mu\text{g}/\text{kg}$  were removed; <sup>b</sup> LOQs of the methods ranging from 0.01 to 25  $\mu\text{g}/\text{kg}$ ; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

14. Table 9 shows the impact of hypothetical MLs for AFs in flour, meal, semolina and flakes derived from maize. Among the five values tested, the data available suggest the establishment of a ML of 20  $\mu\text{g}/\text{kg}$ , considering both the intake reduction (85%; G13) as well as the sample rejection rate (1.0%). If a lower ML were considered, such as 15  $\mu\text{g}/\text{kg}$ , 5.4% of samples of Singapore would be withdrawn from the market. On the other hand, with the adoption of a ML of 10  $\mu\text{g}/\text{kg}$  the rejection rate would exceed 5% for samples submitted by Singapore (6.2%) and would be 5% in samples submitted by the USA.

**Table 9.** Effect of hypothetical MLs on aflatoxins intake through the consumption of flour, meal, semolina and flakes derived from maize for cluster G13 (highest consumption pattern).

ML ( $\mu\text{g}/\text{kg}$ )	Mean lower bound AF ( $\mu\text{g}/\text{kg}$ )	Intake (ng/kg bw per day) <sup>a</sup>	Intake reduction (%)	Sample rejection (%) <sup>b</sup>
No limits	1.84	2.89	-	-
20	0.28	0.44	84.9	1.0
15	0.23	0.36	87.4	1.3
10	0.18	0.28	90.3	1.7
5	0.12	0.19	93.4	2.5
2.5	0.06	0.10	96.6	4.1

<sup>a</sup>Consumption data used: maize, flour (white flour and wholemeal); G13= 94.34 g/person (mean consumption).

<sup>b</sup>Percentage of samples above proposed MLs for considering data submitted by all member countries for this food category.

15. Husked rice. Tables 10, 11 and 12 show data on the occurrence and content of AFs in husked rice. 16% of the 1,018 samples submitted to the GEMS/Food Database were positive for at least one aflatoxin. Mean of positive samples was 16.73 µg/kg, mean and the P95 of the lower bound were 2.67 µg/kg and 8.0 µg/kg, respectively. The USA, Canada and the European Union contributed with the largest dataset of husked rice, representing 30%, 25% and 21% of the samples, respectively. The highest mean level of the lower bound was found in samples submitted by Mali (5.95 µg/kg), USA (5.91 µg/kg) and Thailand (3.47 µg/kg). The highest incidence levels of AFs were found in the years of 2011 (32%) followed by 2017 (30%), 2018 (25%) and 2013 (20%).

**Table 10.** GEMS/Food data on the occurrence and content of AFs in husked rice.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>c</sup>		Lower bound <sup>d</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
Brazil	1/21 (4.8)	0.29 (0.29-0.29)	0.29	0.01	0.00
Canada	7/252 (2.8)	3.59 (0.70-7.60)	2.10	0.10	0.00
European Union	58/215 (27)	3.93 (0.07-27.0)	0.80	1.06	7.61
Indonesia	0/9 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Mali	20/29 (69.0)	8.63 (0.50-26.30)	6.30	5.95	23.52
Singapore	6/49 (12.2)	0.85 (0.18-2.83)	0.39	0.10	0.41
Thailand	22/134 (16.4)	21.16 (0.64-104.02)	1.68	3.47	11.84
USA	49/309 (15.9)	37.37 (0.60-290)	8.00	5.91	17.40
<b>Total</b>	<b>163/1018 (16.0)</b>	<b>16.73 (0.07-290)</b>	<b>4.20</b>	<b>2.67</b>	<b>8.0</b>

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>Samples <LOQ analysed with methods with LOQ higher than 25 µg/kg were removed; <sup>c</sup>LOQs of the methods ranging from 0.004 to 22.5 µg/kg; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 11.** GEMS/Food data on the occurrence and content of AFs in husked rice organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
2011	41/128 (32.0)	7.74 (0.20-26.3)	6.90	2.48	12.13
2012	5/44(11.4)	5.16 (0.40-9.10)	4.20	0.59	4.11
2013	15/74 (20.3)	9.68 (0.29-71)	1.30	1.96	8.59
2014	10/81 (12.3)	34.45 (0.35-290)	2.39	4.25	2.83
2015	12/176 (6.8)	10.50 (0.60-82.11)	2.88	0.72	1.39
2016	10/130 (7.7)	35.47 (0.18-132)	4.35	2.73	1.19
2017	34/114 (29.8)	9.72 (0.20-129)	0.50	2.90	5.84
2018	20/80 (25.0)	20.15 (0.07-104.02)	2.86	5.04	24.65
2019	11/95 (11.6)	57.30 (0.60-150)	12.55	6.63	19.14
2020	4/89 (4.5)	11.23 (1.00-22.3)	10.80	0.50	0.0
2021	1/7 (14.3)	0.75 (0.75-0.75)	0.75	0.11	0.52
<b>Total</b>	<b>163/1018 (16.0)</b>	<b>16.71 (0.07-290)</b>	<b>4.20</b>	<b>2.67</b>	<b>8.0</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 25 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.004 to 22.5 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 12.** GEMS/Food data on the occurrence and content of AFs in husked rice, organized by continent.

Continent	Number and proportion of positive samples <sup>a</sup>  (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean	Median	Mean	P95
Africa	20/29 (69.0)	8.63 (0.50-26.3)	6.30	5.95	23.52
America	57/582 (9.8)	32.49 (0.29-290)	7.00	3.18	7.00
Asia	28/192 (14.6)	16.81 (0.18-104.02)	1.44	2.45	2.69
Europe	58/215 (27.0)	3.93 (0.07-27)	0.80	1.06	7.61
<b>Total</b>	<b>163/1018 (16.0)</b>	<b>16.71 (0.07-290)</b>	<b>4.20</b>	<b>2.67</b>	<b>8.0</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 25 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.004 to 22.5 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

16. Table 13 shows the impact of hypothetical MLs for husked rice. The establishment of a ML of 25 µg/kg seems the most adequate value, considering a reduction of 72% in AFs intake for cluster G03, the cluster with the highest reported consumption of rice, and a sample rejection rate of 1.9%. If the committee agrees on the adoption of a ML of 25 µg/kg for husked rice, the rejection rate would not exceed 5% for any set of samples submitted to the GEMS/Food Database. The establishment of a lower ML, such as 20 µg/kg, would withdraw from the market more than 5% of samples analysed in Mali (10.3%) and samples collected in 2018 (6.2%). Therefore, considering food supply worldwide, a ML of 20 µg/kg seems more suitable.

**Table 13.** Effect of hypothetical MLs on aflatoxins intake through the consumption of husked rice for cluster G03 (highest consumption pattern).

ML (µg/kg)	Mean lower bound AF (µg/kg)	Intake (ng/kg bw per day) <sup>a</sup>	Intake reduction (%)	Sample rejection (%) <sup>b</sup>
No limits	2.67	1.38	-	-
25	0.75	0.39	72.1	1.9
20	0.56	0.29	78.9	2.7
10	0.35	0.18	86.8	4.2
5	0.13	0.07	95.3	7.3
2.5	0.06	0.03	97.7	8.7

<sup>a</sup>Consumption data used: rice, husked, dry (incl. paddy rice); G03=31.05 g/person (mean consumption).  
<sup>b</sup>Percentage of samples above proposed MLs for AFs for considering data submitted by all member countries for this food category.

17. Polished rice. Data on the occurrence and content of AFs in polished rice are shown in Tables 14, 15 and 16. About 10 % of 3,422 samples that were uploaded into the GEMS/Food Database were positive for one or more AFs. Mean of positive samples was 1.94 µg/kg, mean and the P95 of the lower bound were, respectively, 0.2 µg/kg and 0.8 µg/kg. Most samples analysed came from three countries: Thailand (38.8%), the European Union (21.7%) and USA (14.2%). The highest mean level of the lower bound was found in samples submitted by Indonesia (0.41 µg/kg), followed by USA (0.35 µg/kg) and Saudi Arabia (0.25 µg/kg). The highest incidence of AFs was found in 2021 (25.0%), 2014 (17.2%), 2011 (15.8%) followed by 2019 (14.0%).

**Table 14.** GEMS/Food data on the occurrence and content of AFs in polished rice.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>b</sup> (%)	Positive samples - µg/kg <sup>c</sup>		Lower bound <sup>d</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
Brazil	2/39 (5.1)	4.37 (3.87-4.87)	4.37	0.22	0.00
Canada	16/291 (5.5)	2.12 (0.23-7.60)	0.64	0.12	1.08
European Union	171/741 (23.1)	0.67 (0.01-7.53)	0.54	0.15	0.80
Indonesia	28/119 (23.5)	1.76 (0.14-6.90)	0.82	0.41	2.59
Montenegro	0/6 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Saudi Arabia	16/400 (4.0)	6.35 (0.01-27.14)	1.37	0.25	0.00
Singapore	3/11 (27.3)	0.82 (0.16-1.65)	0.65	0.22	1.15
Thailand	92/1328 (7.0)	2.10 (0.35-28.89)	1.04	0.15	0.85
USA	21/487 (4.3)	8.23 (0.60-88)	5.00	0.35	0.00
<b>Total</b>	<b>350/3422 (10.2)</b>	<b>1.94 (0.01-88)</b>	<b>0.80</b>	<b>0.20</b>	<b>0.80</b>

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>LOQs of the methods ranging from 0.004 to 22.50 µg/kg; <sup>c</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 15.** GEMS/Food data on the occurrence and content of AFs in polished rice organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
2011	41/260 (15.8)	1.06 (0.20-6.90)	0.80	0.17	0.80
2012	6/225 (2.7)	4.24 (0.60-6.67)	5.00	0.11	0.00
2013	62/582 (10.7)	2.18 (0.08/88)	0.80	0.23	0.80
2014	34/198 (17.2)	1.60 (0.05-16)	0.80	0.27	0.90
2015	25/260 (9.6)	1.61 (0.01-7.53)	0.49	0.15	0.55
2016	65/592 (11.0)	1.96 (0.01-27.14)	0.85	0.22	0.85
2017	17/365 (4.7)	1.92 (0.01-7.60)	1.06	0.09	0.00
2018	57/601 (9.5)	2.85 (0.02-28.89)	1.26	0.27	1.11
2019	28/200 (14.0)	1.61 (0.14-6.90)	0.82	0.23	0.97
2020	12/127 (9.4)	0.76 (0.02-3.07)	0.52	0.07	0.43
2021	3/12 (25.0)	0.73 (0.23-1.02)	0.94	0.18	0.98
<b>Total</b>	<b>343/3183 (10.2)</b>	<b>1.94 (0.01-88)</b>	<b>0.80</b>	<b>0.20</b>	<b>0.80</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.004 to 22.50 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 16.** GEMS/Food data on the occurrence and content of AFs in polished rice, organized by continent.

Continent	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
America	39/817 (4.8)	5.52 (0.23-88)	3.47	0.26	0.48
Asia	140/1858 (7.5)	2.49 (0.01-28.89)	1.06	0.19	0.85
Europe	171/747 (22.9)	0.67 (0.01-7.53)	0.52	0.15	0.80
<b>Total</b>	<b>350/3422 (10.2)</b>	<b>1.94 (0.01-88)</b>	<b>0.80</b>	<b>0.20</b>	<b>0.80</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.004 to 22.50 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

18. The impact of hypothetical MLs for AFs in polished rice is shown in Table 17. Considering the data available, the implementation of a ML of 5 µg/kg seems suitable since it will reduce AFs intake in 53.6% (G09) and would generate a rejection rate of 0.8%. If the Committee agrees with the ML suggested (5 µg/kg), the rejection rate would not exceed 5% for any set of samples submitted to the GEMS/Food Database. If a ML of 2.5 µg/kg was adopted, 6.7% of samples submitted by Indonesia would be rejected.

**Table 17.** Effect of hypothetical MLs on aflatoxins intake through the consumption of polished rice for cluster G09 (highest consumption pattern).

ML (µg/kg)	Mean lower bound AF (µg/kg)	Intake (ng/kg bw per day) <sup>a</sup>	Intake reduction (%)	Sample rejection (%) <sup>b</sup>
No limits	0.20	0.9439	-	-
20	0.15	0.7080	25.0	0.1
10	0.12	0.5830	38.2	0.3
5	0.09	0.4375	53.6	0.8
2.5	0.07	0.3175	66.4	1.5

<sup>a</sup>Consumption data used: rice. Polished. Dry; G09= 262.1 g/person (mean consumption). <sup>b</sup>Percentage of samples above proposed MLs for AFs for considering data submitted by all member countries for this food category.

19. Sorghum. Tables 18, 19 and 20 show data on the occurrence and content of AFs in sorghum grain destined for further processing. 5.6% of the 11,880 samples submitted to the GEMS/Food Database were positive for at least one aflatoxin. Mean of positive samples was 12.69 µg/kg, and the mean and the P95 of the lower bound were 0.71 µg/kg and 5.0 µg/kg. Almost all data of sorghum grain were submitted by the USA (98.6% of the samples). The highest mean level of the lower bound was found in samples submitted by India (10.5 µg/kg). The highest incidence levels of AFs were found in the years of 2021 (42.9%) and 2011 (22.4%).

**Table 18.** GEMS/Food data on the occurrence and content of AFs in sorghum grain destined for further processing.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>b</sup> (%)	Positive samples - µg/kg <sup>c</sup>		Lower bound <sup>d</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
African Union	5/10 (50.0)	1.99 (0.70-4.36)	1.79	0.99	3.25
Canada	2/43 (4.7)	0.92 (0.83-1.00)	0.92	0.04	0.00
European Union	0/2 (0.0)	<LOQ	<LOQ	<LOQ	0.00
India	11/11 (100.0)	10.54 (6.02-14.82)	10.86	10.54	14.20
Japan	0/5 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Republic of Korea	4/90 (4.4)	5.47 (0.65-10.79)	5.22	0.24	0.00
USA	647/11,719 (5.5)	12.89 (5.00-204)	8.00	0.71	5.00
<b>Total</b>	<b>669/11,880 (5.6)</b>	<b>12.69 (0.65-204)</b>	<b>8.00</b>	<b>0.71</b>	<b>5.00</b>



<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>c</sup>LOQs of the methods ranging from 0.08 to 7.50 µg/kg; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 19.** GEMS/Food data on the occurrence and content of AFs in sorghum grain destined for further processing organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
2011	328/1465 (22.4)	12.60 (5.00-172)	9.00	2.82	15.80
2012	88/792 (11.1)	10.38 (0.65-40)	9.00	1.15	10.00
2013	68/713 (9.5)	9.49 (5.00-37)	8.00	0.90	8.00
2014	34/948 (3.6)	16.91 (5.00-204)	7.00	0.61	0.00
2015	7/1,424 (0.5)	6.00 (5.00-9.00)	6.00	0.03	0.00
2016	51/2,097 (2.4)	11.35 (5.00-82)	7.00	0.28	0.00
2017	19/2,325 (0.8)	9.68 (5.00-27)	9.00	0.08	0.00
2018	24/1,245 (1.9)	6.16 (0.70-12)	6.00	0.12	0.00
2019	37/815 (4.5)	31.08 (5.00-150)	7.00	1.41	0.00
2020	1/28 (3.6)	0.83 (0.83-0.83)	0.83	0.03	0.00
2021	12/28 (42.9)	9.75 (1.00-14.82)	10.21	4.18	13.56
<b>Total</b>	<b>669/11,880 (5.6)</b>	<b>12.69 (0.65-204)</b>	<b>8.00</b>	<b>0.71</b>	<b>5.00</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.08 to 7.50 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero)

**Table 20.** GEMS/Food data on the occurrence and content of AFs in sorghum grain destined for further processing, organized by continent.

Continent	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
Africa	5/10 (50.0)	1.99 (0.70-4.36)	1.79	0.99	3.25
America	649/11762 (5.5)	12.85 (0.83-204)	8.00	0.71	5.00
Asia	15/106 (14.2)	9.19 (0.65-14.82)	9.72	1.30	10.84
Europe	0/2	<LOQ	<LOQ	<LOQ	0.00
<b>Total</b>	<b>669/11,880 (5.6)</b>	<b>12.69 (0.65-204)</b>	<b>8.0</b>	<b>0.71</b>	<b>5.00</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 20 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.08 to 7.50 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

20. Table 21 shows the impact of hypothetical MLs for sorghum grain destined for further processing. The establishment of a ML of 15 µg/kg seems to be reasonable, considering a reduction of 46.5% in AFs intake for cluster G12 and a sample rejection rate of 0.9%. If a ML of 10 µg/kg for sorghum grain destined for further processing was adopted, samples submitted by India and samples collected in 2011 and 2021 would exceed 5% of the rejection rate, representing, respectively, 54.55%, 9.08% and 21.43% of the samples available on the dataset of the category analysed. On the other hand, if the Committee agrees with the ML suggested (15 µg/kg), the rejection rate would not exceed 5% for any set of samples submitted to the GEMS/Food Database, with the exception of 2011 (5.05%).

**Table 21.** Effect of hypothetical MLs on aflatoxins intake through the consumption sorghum grain destined for further processing for cluster G12 (highest consumption pattern).

ML ( $\mu\text{g}/\text{kg}$ )	Mean lower bound AF ( $\mu\text{g}/\text{kg}$ )	Intake ( $\text{ng}/\text{kg}$ bw per day) <sup>a</sup>	Intake reduction (%)	Sample rejection (%) <sup>b</sup>
No limits	0.71	0.0848	-	-
20	0.48	0.0566	33.3	0.4
15	0.38	0.0454	46.5	0.9
10	0.26	0.0306	63.9	1.9
5	0.03	0.0041	95.2	4.9
2.5	0.001	0.0001	99.9	5.6

<sup>a</sup>Consumption data used: sorghum, raw (incl flour. Incl beer); G12= 7.12 g/person (mean consumption).

<sup>b</sup>Percentage of samples above proposed MLs for AFs considering data submitted by all member countries for this food category

Cereal-based food for infants and young children. Data on the occurrence and content of AFs in food for infants and young children are shown in Tables 22, 23 and 24. A total of 3,595 samples were submitted to the GEMS/Food Database, being 10.9% positive for one or more AFs. Mean of positive samples was 2.2  $\mu\text{g}/\text{kg}$ , mean and the P95 of the lower bound were, respectively, 0.24  $\mu\text{g}/\text{kg}$  and 2.5  $\mu\text{g}/\text{kg}$ . Most samples analysed were submitted by the European Union (64.8%), Rwanda (10.8%), Singapore (10.6%) and USA (6.1%). The highest mean level of the lower bound was found in samples submitted by Rwanda (2.06  $\mu\text{g}/\text{kg}$ ). The highest incidence of AFs was found in 2021 (78.5%), followed by the years of 2020 (10.1%), 2014 (9.7%) and 2013 (8.5%).

**Table 22.** GEMS/Food data on the occurrence and content of AFs in cereal-based food for infants and young children.

Country or Region <sup>a</sup>	Number and proportion of positive samples <sup>b</sup> (%)	Positive samples - $\mu\text{g}/\text{kg}$ <sup>c</sup>		Lower bound <sup>d</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
Argentina	0/4 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Brazil	0/38 (0.0)	<LOQ	<LOQ	<LOQ	0.00
Canada	1/140 (0.7)	1.10 (1.10-1.10)	1.10	0.01	0.00
European Union	79/2,329 (3.4)	0.11 (0.004-1.30)	0.05	0.004	0.00
China, Hong Kong SAR	17/50 (34.0)	0.11 (0.01-0.99)	0.02	0.04	0.14
Rwanda	264/389 (67.9)	3.04 (0.43-33.99)	2.80	2.06	3.96
Saudi Arabia	3/39 (7.7)	1.08 (1.08-1.08)	0.23	0.08	1.08
Singapore	11/382 (2.9)	0.20 (0.07-0.33)	0.20	0.01	0.00
Thailand	0/6 (0.0)	<LOQ	<LOQ	<LOQ	0.00
USA	18/218 (8.3)	2.58 (1.05-7.37)	1.63	0.21	1.54
<b>Total</b>	<b>393/3,595 (10.9)</b>	<b>2.20 (0.004-33.99)</b>	<b>2.40</b>	<b>0.24</b>	<b>2.5</b>

<sup>a</sup>Country or region that submitted the data to GEMS/Food; this may not be the country of origin of the food in question; <sup>b</sup>Samples <LOQ analysed with methods with LOQ higher than 10 $\mu\text{g}/\text{kg}$  were removed; <sup>c</sup>LOQs of the methods ranging from 0.002 to 20  $\mu\text{g}/\text{kg}$ ; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 23.** GEMS/Food data on the occurrence and content of AFs in cereal-based food for infants and young children organized by year of sampling.

Year	Number and proportion of positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Median (range)	Median	Mean	P95
2011	2/168 (1.2)	0.15 (0.12-0.18)	0.15	0.002	0.00
2012	0/309 (0.0)	<LOQ	<LOQ	<LOQ	0.00
2013	8/94 (8.5)	0.16 (0.004-1.10)	0.02	0.01	0.02
2014	28/288 (9.7)	0.21 (0.01-1.30)	0.15	0.02	0.09
2015	4/346 (1.2)	0.06 (0.01-0.08)	0.07	0.001	0.00
2016	31/405 (7.7)	1.56 (0.005-7.37)	1.14	0.12	0.20
2017	32/496 (6.5)	3.40 (0.004-33.99)	0.04	0.33	0.01
2018	8/407 (2.0)	0.16 (0.08-0.26)	0.15	0.003	0.00
2019	17/335 (5.1)	0.81 (0.01-3.30)	0.02	0.04	0.004
2020	48/473 (10.1)	1.48 (0.02-6.20)	1.45	0.15	1.44
2021	215/274 (78.5)	2.86 (1.30-4.30)	2.80	2.24	3.80
<b>Total</b>	<b>393/3,595 (10.9)</b>	<b>2.20 (0.004-33.99)</b>	<b>2.40</b>	<b>0.24</b>	<b>2.5</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 10 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.002 to 20 µg/kg; <sup>c</sup>LOQs of the methods ranging from 0.002 to 20 µg/kg; <sup>d</sup>LB: mean of all samples (samples below LOQ were considered as zero).

**Table 24.** GEMS/Food data on the occurrence and content of AFs in cereal-based food for infants and young children, organized by continent.

Continent	Number and proportion or positive samples <sup>a</sup> (%)	Positive samples - µg/kg <sup>b</sup>		Lower bound <sup>c</sup> (µg/kg)	
		Mean (range)	Median	Mean	P95
Africa	264/389 (67.9)	3.04 (0.43-33.99)	2.80	2.06	3.96
America	19/400 (9.2)	2.50 (1.05 -7.37)	0.00	0.12	0.00
Asia	31/477 (6.5)	0.23 (0.01-1.08)	0.14	0.02	0.02
Europe	79/2,329 (3.4)	0.11 (0.004-1.30)	0.05	0.004	0.00
<b>Total</b>	<b>393/3,595 (10.9)</b>	<b>2.20 (0.004-33.99)</b>	<b>2.40</b>	<b>0.24</b>	<b>2.5</b>

<sup>a</sup>Samples <LOQ analysed with methods with LOQ higher than 10 µg/kg were removed; <sup>b</sup>LOQs of the methods ranging from 0.002 to 20 µg/kg; <sup>c</sup>LB: mean of all samples (samples below LOQ were considered as zero).

21. Table 25 shows Food Aid data on the occurrence levels and content of AFs in cereal-based food for infants and young children provided by World Food Programme (WFP). 95.9% of the 246 samples submitted to the GEMS/Food provided were positive for at least one aflatoxin. Mean of positive samples was 1.94 µg/kg, the mean and the P95 of the lower bound were 1.86 µg/kg and 5.65 µg/kg. All data provided by WFP were from African countries. The highest mean level of the lower bound was found in samples submitted in 2017 (16.11 µg/kg) and 2021 (14.95 µg/kg).

**Table 25.** Food aid data on the occurrence and content of AFs in cereal-based food for infants and young children provided by World Food Programme (WFP).

Continent (Year)	Number and proportion of positive samples (%)	Positive samples - $\mu\text{g}/\text{kg}^{\text{a}}$		Lower bound <sup>b</sup> ( $\mu\text{g}/\text{kg}$ )	
		Mean (range)	Median	Mean	P95
<b>Africa</b>	<b>236/246 (95.9)</b>	<b>1.94 (0.35-25.0)</b>	<b>1.00</b>	<b>1.86</b>	<b>5.65</b>
(2017)	6/11 (54.5)	12.23 (7.65-16.99)	12.67	6.67	16.11
(2019)	114/114 (100)	1.07 (1.0-3.30)	1.00	1.07	1.00
(2020)	79/80 (98.8)	1.38 (0.43-6.2)	1.00	1.37	2.71
(2021)	37/41 (90.2)	4.1 (0.35-25.0)	1.90	3.7	14.95

<sup>a</sup>LOQs of the methods ranging from 0.002 to 20  $\mu\text{g}/\text{kg}$ ; <sup>a</sup>LB: mean of all samples (samples below LOQ were considered as zero).

22. The impact of hypothetical MLs for AFs in food for infants and young children is shown in Table 26. Dietary exposure to AFs through the consumption of food for infants and young children was estimated using Canadian Community Health Survey data since worldwide consumption information for this group is not available. The dietary exposure estimate was evaluated for children from 6–11 months and for 1–3 years of age.
23. Considering the data available, both from the GEMS/Food Database and from WFP, the implementation of a ML of 10  $\mu\text{g}/\text{kg}$  would result in a rejection rate of 0.14% of samples available at the international trade and 3.7% of samples analysed by WFP. If a stricter limit was adopted, such as 3  $\mu\text{g}/\text{kg}$  (the highest limit with a rejection rate lower than 5%), samples submitted by Rwanda and samples collected in 2021 would exceed 5% of the rejection rate, representing, respectively, 20.6% and 25.5% of the samples available on the GEMS/Food dataset for this food category (Table 26). On the other hand, if the adoption of a ML of 3  $\mu\text{g}/\text{kg}$  was considered in the data submitted by WFP, 8.1% of samples would be withdrawn from the market, representing 54.5% of samples analysed in 2017 and 26.8% of samples from 2021 (Table 27).

**Table 26.** Effect of the implementation of different MLs for aflatoxins in cereal-based food for infants and young children (only cereal based foods).

ML ( $\mu\text{g}/\text{kg}$ )	Mean lower bound AF ( $\mu\text{g}/\text{kg}$ )	Intake / 6-11 months <sup>a</sup> (ng/kg bw per day)	Intake / 1-3 years <sup>a</sup> (ng/kg bw per day)	Intake reduction (%)	Sample rejection <sup>b</sup> (%)
No limits	0.241	0.8021	0.7250124	-	-
10	0.216	0.7183	0.6493	10.4	0.14
8	0.214	0.7110	0.6426	11.4	0.17
5	0.206	0.6852	0.6194	14.6	0.28
4	0.193	0.6418	0.5801	20.0	0.61
3.5	0.173	0.5762	0.5208	28.2	1.17
3	0.119	0.3971	0.3590	50.5	2.92
2.5	0.052	0.1747	0.1579	78.2	5.37
2	0.023	0.0753	0.0680	90.6	6.65
1.5	0.012	0.0402	0.0364	95.0	7.23
1	0.004	0.0137	0.0	98.3	7.84

<sup>a</sup>Consumption data used: Canadian Community Health Survey, food group 52A, baby food-cereal and baby food-snack results, dry basis (reconst.factor 3.7x or 0.27 assumed for already wet/reconstituted products); 6-11 months=27.52 g/day or 3.33 g/kg bw (mean eaters-only consumption). <sup>b</sup>Percentage of samples above proposed MLs for AFs considering samples from data submitted by all member countries for this food category.

**Table 27.** Sample rejection (%) estimated for each ML proposed for aflatoxins in cereal-based food for infants and young children (only cereal based foods) for each country.

Country	ML ( $\mu\text{g}/\text{kg}$ )									
	10	8	5	4	3.5	3	2.5	2	1.5	1
Argentina	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Brazil	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Canada	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.7
European Union	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
China, Hong Kong SAR	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rwanda	1.3	1.5	2.1	3.3	8.7	20.6	43.7	57.8	62.7	66.3
Saudi Arabia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.7
Singapore	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Thailand	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
USA	0.0	0.0	0.9	0.9	0.9	1.8	2.3	2.8	3.2	5.5

**Table 28.** Sample rejection (%) estimated for each ML proposed for aflatoxins in cereal-based food for infants and young children (only cereal based foods) for each country.

Food aid data (Region/year)	ML ( $\mu\text{g}/\text{kg}$ )									
	10	8	5	4	3.5	3	2.5	2	1.5	1
Africa (total data)	3.7	4.5	5.3	5.3	6.1	8.1	11.8	15.4	20.7	26.0
2017	36.4	45.5	54.5	54.5	54.5	54.5	54.5	54.5	54.5	54.5
2019	0.0	0.0	0.0	0.0	0.0	0.9	2.6	3.5	4.4	4.4
2020	0.0	0.0	1.3	1.3	2.5	2.5	8.8	12.5	25.0	38.8
2021	12.2	14.6	14.6	14.6	17.1	26.8	31.7	43.9	48.8	53.7

24. Even though higher intake reduction could be achieved with the establishment of MLs lower than 10  $\mu\text{g}/\text{kg}$  for cereal-based food for infants and young children, this limit is being recommended considering the input of Food Aid Agencies. They pointed out that high rejection rates in samples submitted by African countries could greatly impact the humanitarian food assistance, since most of the products used for this purpose are produced in the African Region. They also highlighted that if there are less food meeting the MLs available in the market it would create a product shortage and a delay in food supply to humanitarian nutritional programs. Lastly, even if the proposed limit (10  $\mu\text{g}/\text{kg}$ ) is rejecting more than 5% of samples analysed by WFP in 2017 and 2021, the establishment of this limit is in accordance with the request of Food Aid Agencies, since they have already reported the adoption of a ML of 10  $\mu\text{g}/\text{kg}$  for cereal-based food for infants and young children utilized by humanitarian agencies.
25. Considering all data available at the GEMS/Food Database and the scenarios tested above, the following MLs are being suggested for total AFs. The proposed MLs for each food category were based both on the intake reduction and sample rejection (less than 5%). Those MLs are a reasonable choice for the food categories selected, since they greatly contributed to AFs intake reduction and did not result in a large withdrawal of samples from international trade.

**Table 29.** MLs proposed for total aflatoxins in cereals and cereal-based products.

<sup>26</sup> Food category	ML <sup>a</sup>	Sample rejection (%)
Maize grain, destined for further processing <sup>b,c</sup>	30 $\mu\text{g}/\text{kg}$	3.7
Flour, meal, semolina and flakes derived from maize	20 $\mu\text{g}/\text{kg}$	1.0
Husked rice	25 $\mu\text{g}/\text{kg}$	1.9
Polished rice	5 $\mu\text{g}/\text{kg}$	0.8
Sorghum grain, destined for further processing <sup>a</sup>	15 $\mu\text{g}/\text{kg}$	0.9
Cereal-based Food for infants and young children <sup>d</sup>	10 $\mu\text{g}/\text{kg}$	0.14

<sup>a</sup>Limits proposed on an “as is” basis; <sup>b</sup>“Destined for further processing” means intended to undergo an additional processing/treatment that has proven to reduce level of AFs before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels; <sup>c</sup>Does not apply to maize destined for animal feed; <sup>d</sup>All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months).

27. The fact that the MLs suggested above were proposed based on data available at the GEMS/Food Database, submitted mainly by European Union and the USA is a drawback, since it may not be representative of AFs occurrence in cereal-based staple foods across all the GEMS/Food Cluster Diets. However, considering that calls for data on AFs in cereals and cereals-based products have been issued repeatedly since 2014, and a more representative dataset did not become available, it is reasonable that MLs for these food groups should be established based on the present dataset despite its shortcomings, considering the toxicological relevance of the implementation of these maximum levels in order to reduce AFs exposure worldwide.

**Annex I of Appendix II: GEMS/Food 17 Cluster****Table 1.** Countries included in each GEMS/Food Cluster Diets.

<b>Cluster</b>	<b>Countries</b>
<b>G01</b>	Afghanistan, Algeria, Azerbaijan, Iraq, Jordan, Libya, Mauritania, Mongolia, Morocco, Occupied Palestinian Territory, Pakistan, Syrian Arab Republic, Tunisia, Turkmenistan, Uzbekistan, Yemen
<b>G02</b>	Albania, Bosnia and Herzegovina, Georgia, Kazakhstan, Kyrgyzstan, Montenegro, Republic of Moldova, Ukraine
<b>G03</b>	Angola, Benin, Burundi, Cameroon, Congo, Côte d'Ivoire, Democratic Republic of the Congo, Ghana, Guinea, Liberia, Madagascar, Mozambique, Paraguay, Togo, Zambia
<b>G04</b>	Antigua and Barbuda, Bahamas, Barbados, Brunei Darussalam, French Polynesia, Grenada, Israel, Jamaica, Kuwait, Netherlands Antilles, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Saudi Arabia, United Arab Emirates
<b>G05</b>	Argentina, Bolivia, Brazil, Cape Verde, Chile, Colombia, Costa Rica, Djibouti, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Honduras, India, Malaysia, Maldives, Mauritius, Mexico, New Caledonia, Nicaragua, North Macedonia, Panama, Peru, Seychelles, South Africa, Suriname, Tajikistan, Trinidad and Tobago, Venezuela
<b>G06</b>	Armenia, Cuba, Egypt, Greece, Iran, Lebanon, Turkey
<b>G07</b>	Australia, Bermuda, Finland, France, Iceland, Luxembourg, Norway, Switzerland, United Kingdom, Uruguay
<b>G08</b>	Austria, Germany, Poland, Spain
<b>G09</b>	Bangladesh, Cambodia, China, Democratic People's Republic of Korea, Guinea Bissau, Indonesia, Lao People's Democratic Republic, Myanmar, Nepal, Philippines, Sierra Leone, Thailand, Timor Leste, Viet Nam
<b>G10</b>	Belarus, Bulgaria, Canada, Croatia, Cyprus, Estonia, Italy, Japan, Latvia, Malta, New Zealand, Republic of Korea, Russian Federation, United States of America
<b>G11</b>	Belgium, Netherlands
<b>G12</b>	Belize, Dominica
<b>G13</b>	Botswana, Burkina Faso, Central African Republic, Chad, Eswatini, Ethiopia, Gambia, Haiti, Kenya, Malawi, Mali, Namibia, Niger, Nigeria, Senegal, Somalia, Sudan, United Republic of Tanzania, Zimbabwe
<b>G14</b>	Comoros, Fiji Islands, Kiribati, Papua New Guinea, Solomon Islands, Sri Lanka, Vanuatu
<b>G15</b>	Czechia, Denmark, Hungary, Ireland, Lithuania, Portugal, Romania, Serbia, Slovakia, Slovenia, Sweden
<b>G16</b>	Gabon, Rwanda, Uganda
<b>G17</b>	Samoa, São Tome and Principe

**Annex II of Appendix II: GEMS/Food Consumption Data****Table 1a.** Consumption data obtained from the GEMS/Food Cluster Diets - G01 to G08 (g/person/day).

<b>Food category</b>	<b>G01</b>	<b>G02</b>	<b>G03</b>	<b>G04</b>	<b>G05</b>	<b>G06</b>	<b>G07</b>	<b>G08</b>
Maize raw	0.6	NC	0.6	NC	1.2	12.3	NC	NC
Maize flour	22.7	35.6	87.3	34.9	46.7	49.1	14.3	12.9
Rice husked	1.2	1.3	31.1	4.8	0.3	2.2	2.4	1.6
Rice polished	34.2	10.4	41.7	82.4	150.2	70.5	13.4	10.8
Sorghum raw	0.0	0.01	0.0	0.01	0.0	0.0	0.0	0.0

NC= no consumption data available.

**Table 1b.** Consumption data obtained from the GEMS/Food Cluster Diets - G09 to G17 (g/person/day).

<b>Food category</b>	<b>G09</b>	<b>G10</b>	<b>G11</b>	<b>G12</b>	<b>G13</b>	<b>G14</b>	<b>G15</b>	<b>G16</b>	<b>G17</b>
Maize raw	1.4	NC	NC	NC	NC	0.01	0.03	NC	NC
Maize flour	19.7	12.5	4.2	52.3	94.3	8.1	28.0	56.0	28.1
Rice husked	0.4	1.1	0.0	5.0	13.5	3.5	2.0	0.01	8.8
Rice polished	266.1	57.2	12.8	62.8	30.2	218.3	12.8	15.2	51.3
Sorghum raw	0.01	1.2	0.0	7.1	0.0	0.0	0.0	0.0	0.0

NC= no consumption data available.



**REFERENCES**

Codex Alimentarius Commission (CAC), 1995. Codex general standard for contaminants and toxins in food and feed – Codex Standard 193-1995. Available at: <http://tinyurl.com/mpkehpr>.

Codex Alimentarius Commission, 2019. DISCUSSION PAPER ON THE ESTABLISHMENT OF MAXIMUM LEVELS FOR TOTAL AFLATOXINS IN CEREALS (WHEAT, MAIZE, SORGHUM AND RICE), FLOUR AND CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN – CX/CF 19/13/15. Available at: [encurtador.com.br/cnPSU](http://encurtador.com.br/cnPSU)

Codex Alimentarius Commission, 2019. REPORT OF THE 13rd SESSION OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS, REP19/CF. Available at: [encurtador.com.br/hsTVW](http://encurtador.com.br/hsTVW)

Codex Alimentarius Commission, 2019. Forty-second Session, REP19/CAC. Available at: [encurtador.com.br/gHTZ8](http://encurtador.com.br/gHTZ8)

FAO/WHO, 1998. Joint FAO/WHO Expert Committee on Food Additives - Evaluation of certain food additives and contaminants: forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 40. WHO Food Additives Series, p. 73.

FAO/WHO, 2017. Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Evaluation of certain food contaminants: eighty-third report of the Joint FAO/WHO Expert Committee on Food Additives. vol. 1002. WHO technical report series, Rome, Italy, p. 182

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